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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/25/2003

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/25/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/321,882

Applicant(s)

UPASANI ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25-27, 46, 55, 57, 59, 66 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) 66 and 70 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 and 59 is/are allowed.
- 6) ☒ Claim(s) 25, 46, 55, 57 and 71 is/are rejected.
- 7) ☒ Claim(s) 26 and 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Status of the Application***

2. Claims 25-27, 46, 55, 57, 59, 66 and 69-71 are pending in the present application. Claims 25-27, 46, 55, 57, 59, 69 and 71 will be examined to the extent they read on the elected species and variants thereof (i.e., compounds wherein R<sub>3</sub> is -C(O)-CH<sub>2</sub>-O-D or -C(O)-CH<sub>2</sub>-Y'-Z-G). Claims 66 and 70 stand withdrawn from further consideration as being drawn to a nonelected invention.
3. Applicant's argument to the withdrawn of certain claims is noted. However, the claims are being searched according to MPEP § 803.02.

### ***Claim Objections***

4. The objection to claims 25 and 26 under 37 CFR 1.75(c) is withdrawn.
5. The objection to claim 65 under 37 CFR 1.75(c) is made moot by the cancellation of the instant claim.

***Claim Rejections - 35 USC § 112***

6. The rejection of claims 25, 26, 46, 55, 57, 59 and 69 under 35 USC 112, first paragraph is withdrawn.

7. The rejection of claims 64 and 68 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 25, 46, 55, 57 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillipps et al. ('569).

Phillipps et al. teach steroids of the 5 $\alpha$ -pregnane series possessing a 3 $\alpha$ -hydroxy group, an 11-oxo group, a 17 $\alpha$ -hydrogen atom, a 20-oxo group and a group of formula –XR at the 21-position (see the entire article, especially col. 2, lines 32-61). The reference teaches the preferred compounds are those wherein XR is an –OC(O)R group and R is pyridyl (see attached CAS Abstract, RN 38392-72-2). The reference teaches the compounds possess anaesthetic properties (see Abstract, col. 1, line 63 –

co. 2, line 12). The compounds and compositions taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

**10. The rejection of claims 25-27, 46, 55, 57 and 59 under 35 USC 103(a) over Bolger et al. ('917) is withdrawn.**

**11. The rejection of claims 58, 61, 64 and 65 under 35 USC 103(a) over Bolger et al. ('917) is made moot by the cancellation of the instant claims.**

**12. The rejection of claims 25-27, 46, 55, 57 and 59 under 35 USC 103(a) over Phillipps et al. ('260) is withdrawn.**

**13. The rejection of claims 58, 61, 62 and 68 under 35 USC 103(a) over Phillipps et al. ('260) is made moot by the cancellation of the instant claims.**

***Allowable Subject Matter***

**14. Claims 26 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.**

**15. Claims 27 and 59 are allowed.**

***Other Matters***

16. Claim 59 contains a typographical error. It recites the phrase "pharmaceutical compound" and should be rewritten as "pharmaceutical composition".

***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


***Telephone Inquiry***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
September 23, 2003